

Tel. 248-624-0347 [Res.]
248-442-5112 [Bus.]

Peter A. Fulda
30984 Springlake #20308
Novi, MI 48377

August 2, 2000

Dockets Management Branch
HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Docket No. 98F-0165

2700 '00 AUG 16 P3:05

Re: Irradiation in the Production, Processing and Handling of Eggs

I appreciate this opportunity to submit written objections and to request a hearing concerning the Food and Drug Administration's decision to legalize the irradiation of eggs. I request that implementation of the new regulation be delayed and that a public hearing be held.

My objection focuses on the fact that the irradiation of eggs is an intervention strategy, which fails to address primary causes of Salmonella enteritidis - contaminated eggs. Irradiation falsely implies that eggs are inherently unwholesome products that can only be made "clean" and "safe" by complicated nutrient depleting technologies like irradiation. In reality, (a) hens' eggs have virtually full-proof many-layered barriers against pathogens given that, in nature, hens' eggs are intended to hatch healthy chicks (CDC, 1990; Davis, 1996); and (b) chronically stressed, immunocompromised hens are laying contaminated eggs for human consumption in crowded, filthy buildings and are subjected to a variety of disease-inducing practices including stressful lighting programs and the intentional starvation of the hens known as forced molting. These practices impair hens' immune systems, predisposing them to Salmonella infection. Irradiation masks these primary causes of Salmonella enteritidis (SE) in eggs, and, I am assured, it won't even do that.

Short Background: Salmonella enteritidis has pathologically migrated from hens' intestines to their oviducts where it can be an infectious ingredient in eggs as they are being formed inside the hen.

Crowded concentrations of hens in confinement during the past 40+ years is linked to the fact that a specific type of Salmonella - Salmonella enteritidis- has developed that can live not only in the intestines but in the ovaries and oviducts of hens used for egg production. SE infects eggs as they are being formed inside the hen (CDC, June 8, 1990). According to Avian Diseases (1996), "Although salmonellas are widespread in nature, the

.../2

HER 2

98F-0165

intensification of livestock production has led to an increased risk of clinical and subclinical salmonella infection. The pyramidal structure of the poultry industry has provided an opportunity for dissemination and persistence of *Salmonella enteritidis*, particularly phage type 4, which has resulted in an epidemic increase in human salmonella food poisoning cases caused by consumption of egg or poultry meat products" (Davies and Wray, 1995).

Objections to Irradiation of Eggs

Both government and industry point out that irradiation of eggs cannot substitute for sanitation, or for recommended packaging, refrigeration, cooking, and serving of eggs. "Irradiation of fresh shell eggs at the doses requested in the petition will reduce, but not entirely eliminate, microorganisms in eggs," according to the Federal Register, July 21, 2000. Moreover, these microorganisms can grow back from a few to many despite irradiation. Notwithstanding, irradiation has been approved as a compensation for poor sanitation and pathogen-promoting economic practices at the farm level. Additionally, compensation for the fact that hens used by the egg industry are pathologically susceptible to infected ovaries and oviducts from a microorganism whose normal habitat is the intestinal tract. It appears that for the egg industry, an attractive feature of irradiation is its ability to extend the shelf life of eggs by reducing bacterial spoilage. I.e., old, irradiated, vitamin-depleted eggs can sit there a week or so longer with "fresh" stamped on the carton. Meanwhile, the most targeted pathogen, SE, has been shown to be the most irradiation resistant type of *Salmonella* (Brown, 1994) following exposure to approved levels of radiation of meat and eggs up to 3.0 kiloGrays (kGy).

Filthy Laying Environment

This filth includes not only the manure dripping down and encrusting the bars of the wire cages and piling up in the pits beneath the cages. It includes the toxic excretory ammonia gases from the decomposing uric acid in the manure – gases that can range dangerously between 60 and 200 ppm in crowded chicken houses (Davis, 1996). The high levels of ammonia not only permeate egg shells; they predispose the hens to immunosuppression and to airborne pathogens including *Salmonella* as a result of the excessive mucous that accumulates in the birds' trachea in response to the ammonia overload. Irradiation ignores the disease-producing filth and toxicity in the hens' environment that predispose them and their eggs to *Salmonella enteritidis* in the first place (Davis, 1996).

Stressful Lighting Programs

Fifty-two weeks of 15-17-day lighting schedules (mimicking the longest days at the peak of summer) force commercial laying hens to lay an abnormally large number of eggs

based on the fact that, in nature, egg-laying is hormonally synchronized with the lengthening and shortening of days (North & Bell, 1990). The harsh artificial lighting schedule is a primary cause of immunosuppression in the hens, making them susceptible to Salmonella infection (Smith, 1994). Irradiation does not address this immunosuppressive, pathogen-inducing practice but, rather, encourages it to continue.

Forced Molting (Prolonged Starvation of Hens)

Forced molting is a starvation practice employed by the US egg industry to manipulate egg laying and the economics of production. It involves the removal of ALL food from hens used for commercial egg production for 5 to 14 days (typically 10 to 14 days) to manipulate the hormones responsible for egg production and feather cover. Forced molting is designed to force the birds to lose 25 to 30 percent of their body weight, particularly the abnormal fat which accumulates in their oviducts from lack of exercise and related stresses of confinement (Davis, 1996; United Poultry Concerns, Petition to FDA [Docket No. 98P-0203/CP1], April 14, 1998).

According to the US Department of Agriculture, "[Extended] starvation and water deprivation practices lead to increased shedding of Salmonella enteritidis (Se) by laying hens subjected to these practices" (Stolfa, August 21, 1998). USDA further states: There is epidemiologic evidence which associates [forced] molting with higher prevalence of SE in flocks. Molted SE-positive flocks also seem to produce SE-positive eggs more frequently than their non-molted counterparts. Experimentally, Holt et al. (1996, 1995, 1994, 1993, 1992) have demonstrated that molting is associated with increased numbers of SE in hens' intestinal tracts, and higher rates of SE-positive eggs are produced following molt. Schlosser et al. (1995) demonstrated similar results in a field study during the Pennsylvania Pilot Project. In that study [which comprised 31 flocks from May 1, 1992 to May 1, 1994] molted flocks produced SE-positive eggs twice as frequently as non-molted flocks for a period up to 140 days following molt (Salmonella Enteritidis Risk Assessment-Shell Eggs and Egg Products, June 12, 1998; Aug. 10, 1998, p. 40).

In April of 1998, United Poultry Concerns and the Association of Veterinarians for Animal Rights filed a Citizen Petition with the Food and Drug Administration (Docket No. 98P-0203/CP1) requesting the FDA to prohibit forced molting based on the FDA's authority to prohibit farming practices that have been shown to harm human health. Forced molting has been shown in both laboratory and field studies to increase hens' susceptibility to Salmonella enteritidis infection. Yet despite scientific documentation showing the link between forced molting and SE infection of hens and their eggs, including the USDA Farm Animal Well-Being Task Group Meeting documents of July

21, 1998, obtained by United Poultry Concerns through a Freedom of Information Act request, the FDA has failed to take action (Troxell, September 30, 1999).

Instead, the Food and Drug Administration ignored the Citizen Petition, while granting Edward S. Josephson's petition to irradiate eggs, although, according to a News Release published by the health research group Public Citizen, on July 24, 2000, radiation "treatment" of eggs will deplete vitamins, disrupt proteins, and mask factory farm filth. Public Citizen says in its News Release that "The request to irradiate eggs was made by Edward Josephson, who during the 1960s and 1970s oversaw the U.S. Army's food irradiation headquarters in Massachusetts, where dozens of studies revealed serious health problems in lab animals that ate irradiated food, including premature death and cancer."

Public Citizen is challenging the Food and Drug Administration's use of three laboratory rodent studies which the FDA says satisfied the agency that the petitioned use of irradiation on fresh shell eggs "raises no toxicity concerns" (Federal Register, July 21, 2000, pp. 45280-82). Public Citizen indicates otherwise.

Conclusion

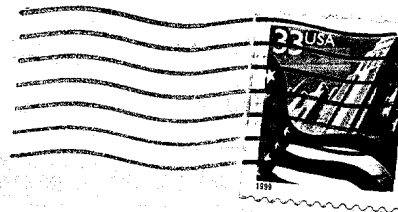
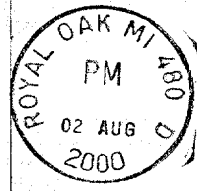
I request the FDA to delay implementation of the regulation and to hold a public hearing on the agency's decision to legalize the irradiation of eggs. I object to the fact that the FDA refuses to regulate practices that predispose hens and their eggs to SE in the first place, while telling consumers that, for example, vitamin depletion in eggs can be made up for in other foods, when, in fact, an increasing number of other foods are being irradiated and are thus similarly nutritionally compromised. In addition to the filthy buildings in which the eggs destined for irradiation are laid by Salmonella-disposed, inhumanely treated hens, irradiation will be added to these eggs, along with vitamin depletion and unappealing visual and textural characteristics. All this, plus all those "little changes" in the fatty acids, "structure," "digestibility," and "biological value of protein" noted in the Federal Register notice of July 21, indicates that a public hearing should be held as soon as possible to discuss the synergies and implications of all these "little changes." Concern is serious given the fact that irradiation will not reduce the need to treat eggs like Salmonella-contaminated products that can cause acute illness, chronic arthritis, and other systemic degenerative diseases and possibly fatal illnesses in babies, in the growing population of elderly people, and in the large number and diversity of people of all ages with susceptible immune systems (CAST, September 1994).

Yours truly,



Peter Fulda

Peter Fulda
30984 Springlake #20308
Nov, MI 48377



DOCKETS MANAGEMENT BRANCH
HFA-305
FOOD & DRUG ADMINISTRATION
5630 FISHERS LANE, ROOM 1061
ROCKVILLE, MD 20852

20851+2481